DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

FEB 06 2004

Date:

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Ganoderma lucidum Mycelium Powder

Firm: Atlantic Medical Health Care, Inc.

Date Received by FDA: July 16, 2003

90-Day Date: Oct 16, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya L. Jackson
IDSI Botanist

95S-0316

RPT202

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, Maryland 20740

SEP 26 2003

Mr. Michael J. O'Flaherty
1400 Sixteenth Street, N. W.
Suite 400
Washington, D.C. 20036-2220

Dear Mr. O'Flaherty:

This is to inform you that the notification, dated July 14, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) was filed by the Food and Drug Administration (FDA) on July 16, 2003. Your notification identified Ganoderma lucidum mycelium as the new dietary ingredient in the dietary supplement product "Feeling Wel Ganoderma Essence".

Your notification states that the dietary supplement, "Feeling Wel Ganoderma Essence" will be marketed in capsule form. Each capsule would contain 500 mg with 400 mg being the mycelium powder and 100 mg gelatin film. The notification also states that the components in each 500 mg capsule are Ganoderma polysaccharides (30 mg), ganodermic acids (4 mg) and selenium (14 mcg). The notification indicates that the conditions of use recommended or suggested for the "Feeling Wel Ganoderma Essence" is 1-2 capsules per day before a meal. The dietary supplement label will state that the supplement is "not recommended for pregnant women and transplant recipients. Keep out of reach of children."

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully evaluated the information in your submission and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Ganoderma lucidum mycelium will reasonably be expected to be safe. The notification states that Ganoderma lucidum is a traditional Chinese Herb Supplement that has been used by the Chinese and Japanese for over 2000 years. However, the notification fails to differentiate between the fruiting body (mushroom) form of Ganoderma lucidum, which has an established history of use in China, and the hyphae (mycelium) form of the fungus Ganoderma lucidum which is a new dietary ingredient and does not have a history of use. The notification states that each "Feeling Wel Ganoderma Essence" capsule (500 mg) contains 400 mg of Ganoderma lucidum mycelium powder and 100 mg gelatin film. However, the packaging description states that each capsule will weigh 380 mg (0.38 g). In addition, the notification includes a 30-day pre-clinical study. However, the results of a 30-day toxicity study in rodents is insufficient to establish evidence of safe daily human consumption of Ganoderma lucidum mycelium powder.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that Ganoderma lucidum mycelium powder in the "Feeling Wel Ganoderma Essence" product, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of July 16, 2003. After the 90 day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

FOR

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

OLSSON, FRANK AND WEEDA, P.C.
ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER

TISH E. PAHL
ROBERT A. HAHN
NAOMI J. L. HALPERN
STEPHEN L. LACEY
SHARON D. BROOKS
RYAN W. STROSCHEIN
EVAN P. PHELPS
VALERIE B. SOLOMON*

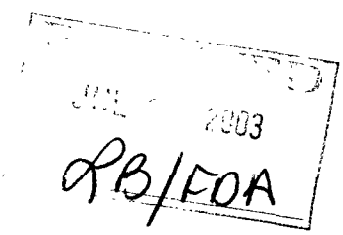
OF COUNSEL
JUR T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF

Sender's Direct Phone (202) 518-6320
Sender's Direct Facsimile (202) 234-2686

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES

July 14, 2003

BY FEDERAL EXPRESS



Dr. Christine Lewis Taylor
Director
Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740-3835

Re: New Dietary Ingredient Notification

Dear Dr. Taylor:

Enclosed for filing, on behalf of Atlantic Medical Health Care, Inc. (the company), pursuant to 21 U.S.C. § 350b(a)(2) and 21 C.F.R. § 190.6, is notification of a new dietary ingredient, Ganoderma lucidum Mycelium Powder, intended for use in a dietary supplement, FeelingWel Ganoderma Essence®, to be distributed by the company. The notification conveys evidence of safety providing the basis upon which the company has concluded that the dietary supplement containing such dietary ingredient, when used under the conditions recommended in the labeling of the dietary supplement, will reasonably be expected to be safe.

The company previously has submitted notification of its new dietary ingredient. That notification was filed on March 26, 2003. In a June 12, 2003 response letter, your Office determined that the information presented in the notification provided an inadequate basis to find the requisite expectation of safety, citing specific deficiencies. The current submission has been revised to address those deficiencies and to convey improved information. Please contact me directly with any inquiry or concern about it.

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Your attention to this matter is appreciated.

Respectfully submitted,

Michael J. O'Flaherty
Counsel for Atlantic Medical Health Care, Inc.

MJO:jdm